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(54) Improved protective sheath for a cannula

(57) A protective device for enclosing the scarf (86) of a cannula (70) includes an elongated sheath (82) having a bore (71) extending through it. The cannula (70) is sealed in the bore (71) of the sheath (82) with the scarf end of the cannula (70) located within and adjacent one end of the sheath (82), which is spaced from the scarf (86). The end of the sheath adjacent th scarf end of the cannula has at least one cutout (84) portion which can receive the edge of a flexible bag or a flexible tubing connected to a Y-site for intravenous injection. A socket (92) carried by the sheath (82) at the other end of the cannula (70) has an opening through it in communication with the bore (71) through the cannula (70). The socket opening (92) tapers outwardly away from the cannula (70) for receiving a tapered nozzle on a syringe.

Preferably, the sheath (82) surrounds the socket (92) and carries inwardly extending ears (96) which act as male threads for engaging internal threads in a skirt around the discharge nozzle of a syringe. The skirt makes a slip fit against the inside of the sheath surrounding the socket and inwardly extending ears. Preferably the outside surface of the syringe skirt is irregular to provide an increased coefficient of friction against the interior surface of the sheath.

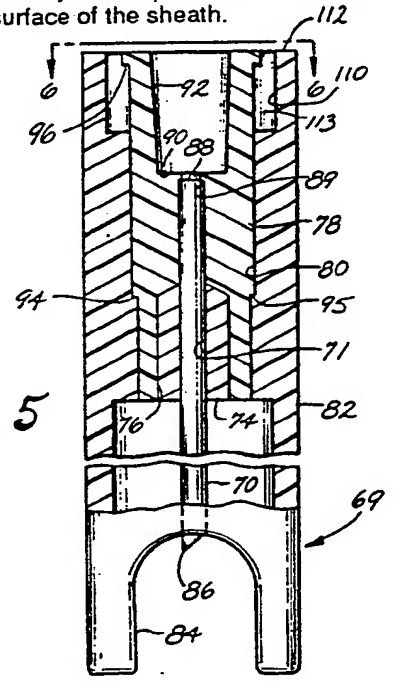

Fig. 5

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Fig. 1

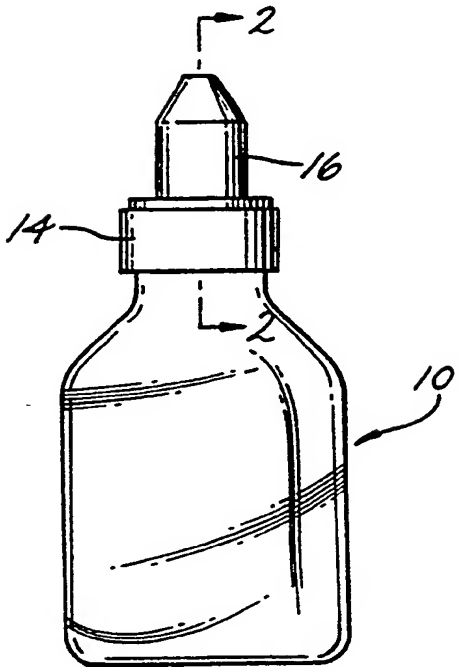


Fig. 2

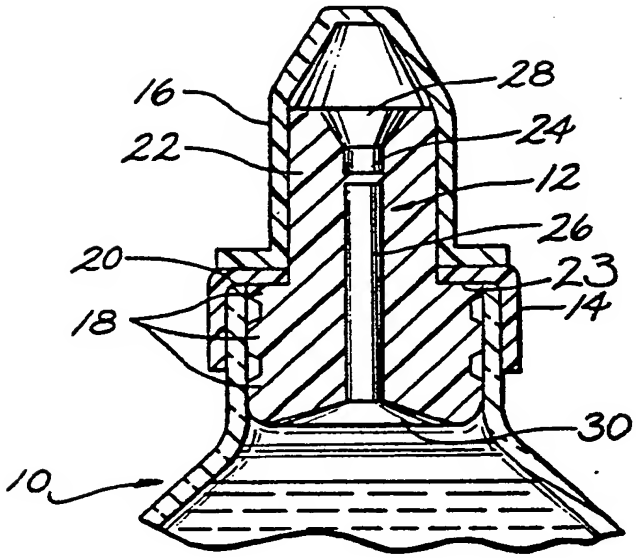


Fig. 3

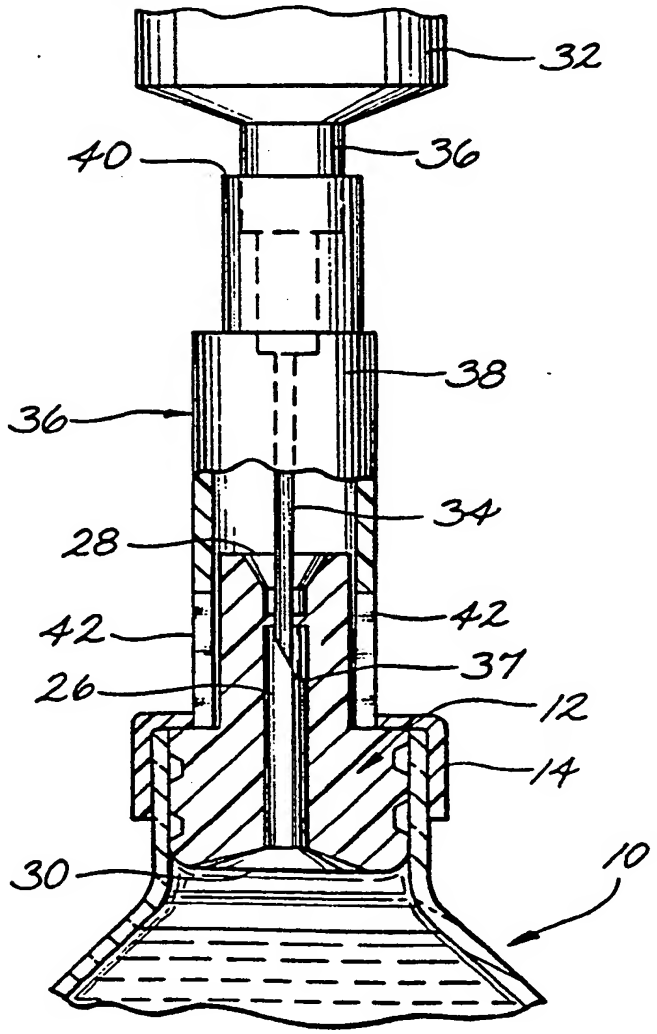


Fig. 4

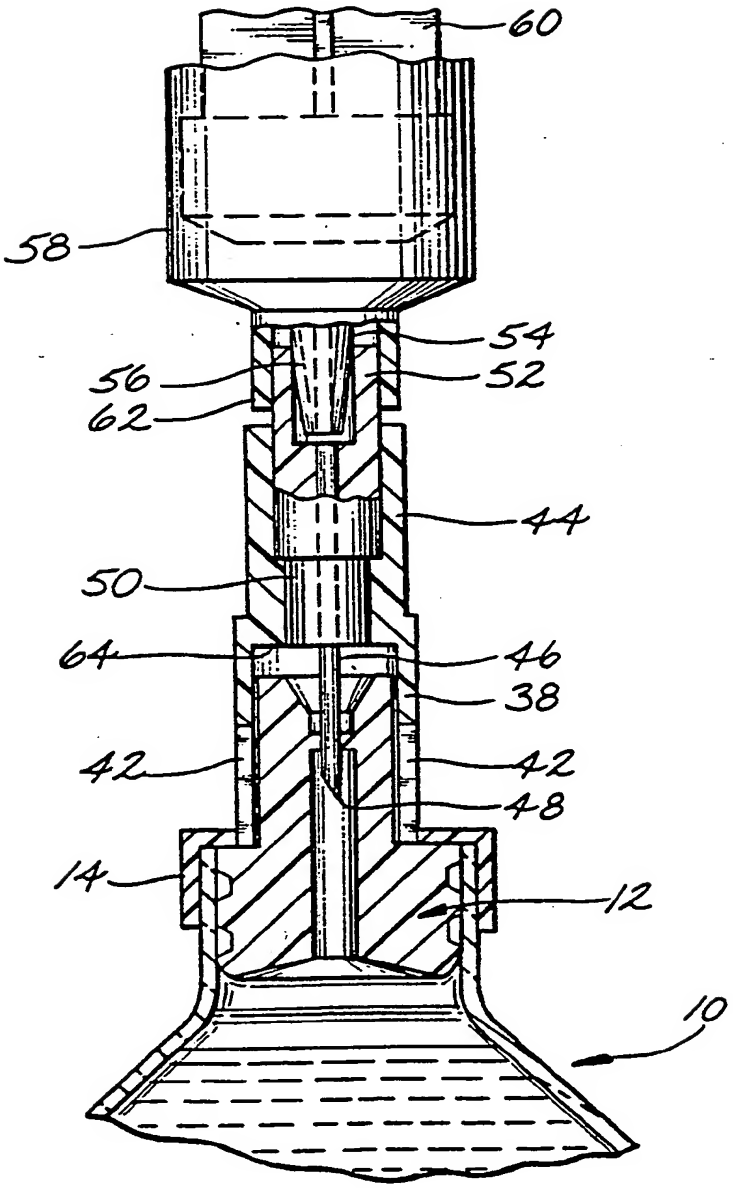


Fig. 8

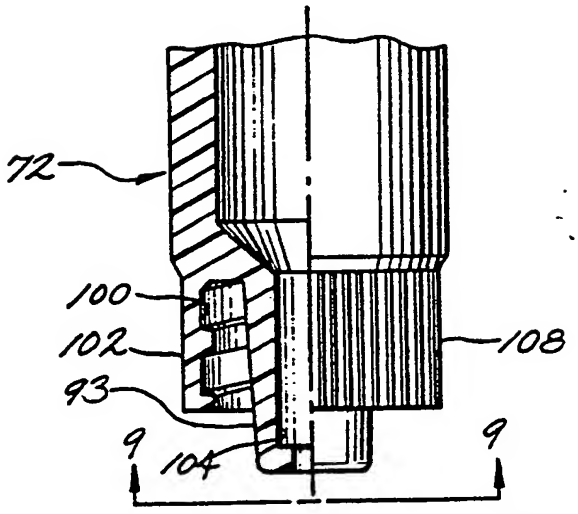
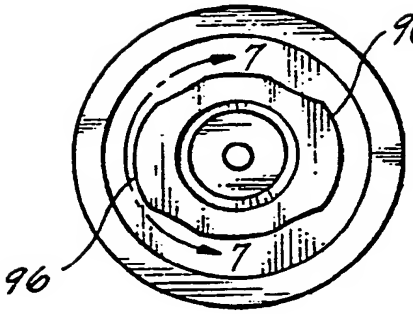


Fig. 6



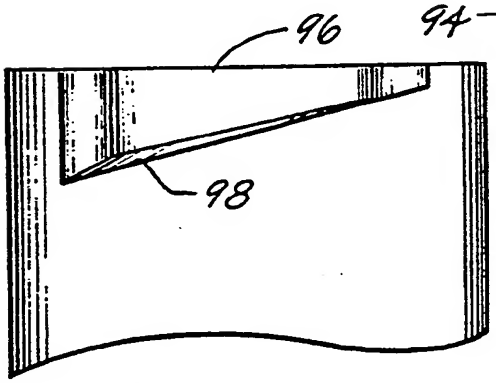


Fig. 7

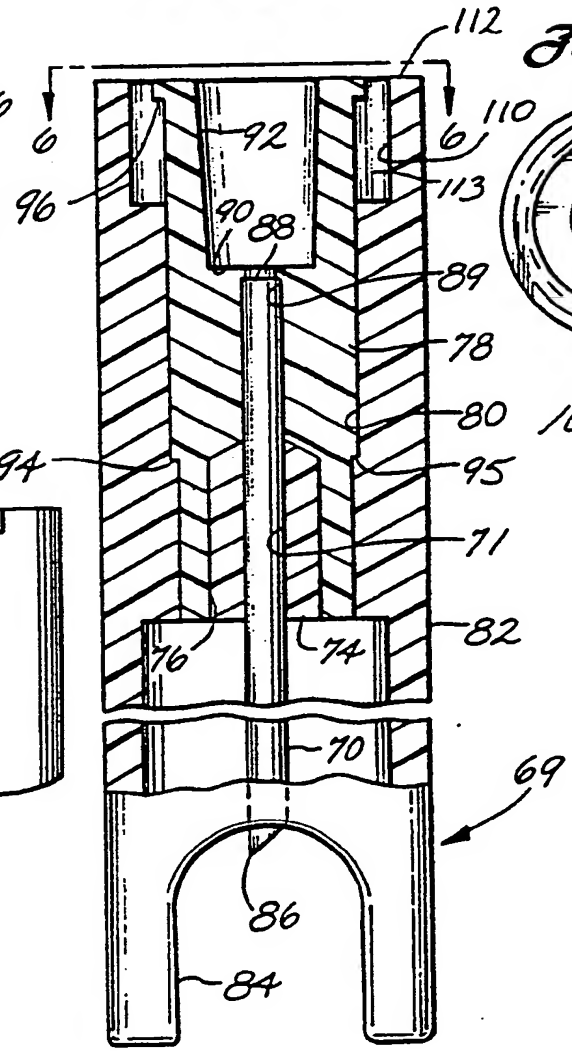
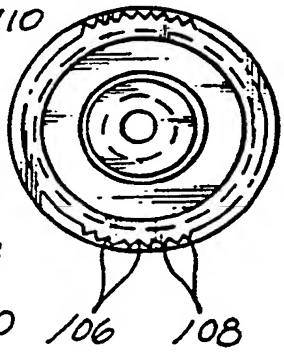


Fig. 5

Fig. 9



IMPROVED PROTECTIVE SHEATH FOR A CANNULA

This is a continuation-in-part of application Serial No. 07/142,965, filed January 12, 1988, entitled "Package for Toxic and Dangerous Drugs".

A significant number of drugs are toxic, mutagenic, or otherwise dangerous if contacted, or inhaled or ingested, in an uncontrolled or improper manner, by a human being. Health care professionals, including physicians, nurses, and others, are particularly subject to exposure to these hazards. For example, the anti-tumor drugs present these hazards. At present, these drugs are usually sold in glass vials or ampules in either powder or liquid form. If in powder form, the drug must be dispensed in a liquid just before administration. The drug in the liquid state must be transferred to a hypodermic syringe, or a similar device, fitted with a cannula (hollow needle) with a scarf (sharp end) for subsequent direct injection into the patient, or for addition to an intravenous solution bottle or bag to permit infusion of the drug to the patient.

The present invention provides an improved protected cannula for more safely transferring hazardous drugs from

a drug container, to a syringe, and thereafter to a patient. The present invention significantly reduces the risk of inadvertent finger and hand punctures stemming from accidental contact with the scarf of the syringe cannula. Thus, this invention substantially reduces the possibility of unintended exposure to hazardous drugs, or to dangerous viruses, such as hepatitis or AIDS (acquired immune deficiency syndrome), carried by a contaminated cannula.

In another important aspect, this invention also reduces the likelihood of accidental leakage and spillage of the drug onto the hands and fingers, or work surfaces.

Briefly, this invention provides an improved protective device for enclosing the scarf of a cannula, and which can easily be connected to the discharge end of a syringe. The device includes an elongated sheath having a bore extending through it. An elongated cannula with a scarf end is mounted and sealed in the bore of the sheath so the scarf end of the cannula is located within and adjacent one end of the sheath. The end of the sheath adjacent the scarf end of the cannula has at least one cutout portion which can receive the edge of a flexible bag or flexible tubing connected to a Y site for intravenous injection. The sheath includes a socket at the end of the cannula remote from the scarf. The socket has an opening through it so the socket interior is connected to the passage through the cannula. The socket opening tapers outwardly and away from the cannula for receiving a tapered nozzle on a syringe. In the preferred form, the sheath, which is preferably cylindrical, includes two diametrically opposed cutouts, and longitudinal grooves are provided on the outside of the sheath to provide improved gripping for manipulating the device. Preferably, the socket carries laterally extending ears in the shape

of interrupted male threads for engaging an internally threaded skirt on a syringe. The skirt surrounds the syringe nozzle, and is spaced from the nozzle. Preferably, the sheath is disposed around and spaced from the ears and outwardly tapering end of the socket to form an annular space for receiving the skirt on the syringe. Preferably, the outer surface of the skirt makes a friction slip-fit against the inside of the socket, and the outer surface of the skirt is irregular to minimize the possibility of accidental disengagement of the socket from the syringe.

These and other aspects of this invention will be apparent from the following detailed description, taken with the accompanying drawings.

FIG. 1 is a side view of a preferred embodiment of a toxic medicament package constructed for use with the improved protective device of this invention;

FIG. 2 is a view taken on line 2-2 of FIG. 1;

FIG. 3 is a side and partial sectional view showing the use of the protective device to transfer a toxic drug from the package of FIGS. 1 and 2 to a syringe;

FIG. 4 shows, in sectional view, another embodiment of the present invention;

FIG. 5 is an elevational view, partly in cross section, showing the detailed construction of the presently preferred protective device of this invention;

FIG. 6 is a view taken on line 6-6 of FIG. 5;

FIG. 7 is a view taken on line 7-7 of FIG. 6;

FIG. 8 is an elevation, partly in cross section, of the presently preferred embodiment of the discharge end of a syringe adapted to be used with the protective device of this invention; and

FIG. 9 is a view taken on line 9-9 of FIG. 8.

FIGS. 1 and 2 show a preferred medicament package where 10 is a rigid bottle containing toxic medication (not shown), 12 is a stopper, 14 is a crimped metal retainer collar which extends around the bottle 10 and aids in holding stopper 12 in place, and 16 is a protective cover.

The stopper 12 is normally a resilient material, such as rubber, and has a plurality of sealing rings 18 on its lower portion which are received in the open end 20 of the bottle 10. The upper portion 22 of stopper 12 projects beyond the outer extremity of the open end 20 of bottle 10 and generally is smaller in diameter than said lower portion. The transition between the upper and lower portions of the stopper forms an upwardly facing shoulder 23 which abuts the under surface of collar 14. The stopper 12 is provided, preferably within said upper portion 22, with an imperforate diaphragm 24, which bridges a centrally disposed, and longitudinally extending fluid pathway 26. As shown in FIG. 2, the length of the upper portion of the stopper projecting beyond the outer extremity of the open end of the bottle is at least several times greater than the longitudinal thickness of the diaphragm. In addition, the longitudinal thickness of the diaphragm is less than the transverse dimension of the fluid pathway. The upper and lower portions of stopper 12 are collinear and have concave end surfaces 28 and 30, respectively, the centers of which are concentric with said fluid pathway.

The protective cover 16 is held on the outer portion 22 of stopper 12 by a slight interference fit so that the cap will not fall off, but still can be readily removed by hand.

The bottle 10 can be replaced by a cylindrical shell vial, ampule, or the like.

The embodiments of FIGS. 3 and 4 include structure disclosed in applicant's U.S. Patent 4,834,716, issued May 30, 1989., the disclosure of which is expressly incorporated herein by reference.

As shown in FIG. 3, a protective device 36 includes a generally cylindrical sheath 38 forming a closed end 40 by seal or integral formation with a boss 36 of a syringe 32. If the sheath is not integral with the syringe, it can be removable by a slip interference fit on the boss.

The sheath 38 terminates in an open end which is disposed beyond the end of scarf 37 of a cannula 34.

The sheath 38 preferably has two diametrically disposed cutouts 42. One cutout is actually sufficient for connecting the protective device to a Y-site, but two cutouts provide greater convenience to the users, and are required for connecting the device to a port of a bag. The dimensions of cutouts 42 are such as to accommodate the tubular Y-site portion (not shown) of a typical I.V. or "giving set", which is known to those skilled in the art.

The contents of the syringe can be injected into the patient via the Y-site in the usual way, with the important difference being that the health care provider is not apt to suffer an accidental needle puncture in the process of manually manipulating the syringe and Y-site to make the necessary connection to hook-up.

Before use, the sheath 38 can be provided with a removable cap or cover (not shown), forming an aseptic seal with said sheath 38.

In the embodiment shown in FIG. 4, the sheath 44 is a separate piece having cutouts 42 (previously explained), cannula 46, scarf 48, and boss 50 to which cannula 46 is affixed or secured. The boss 50 has a cylindrical projection 52 with an open end 54. The open end 54 is adapted to sealably receiving a Luer fitment 56 of syringe 58 having a conventional reciprocatable plunger 60. The

projection 52 also has, slidably received around it in a snug fit, a Luer skirt 62. The syringe 58 may also have the structure shown in U.S. Patent No. 3,376,866, or U.S. Patent No. 4,737,144, the disclosure of each of which is incorporated herein by reference.

In this way, the toxic or hazardous contents of bottle 10 can be transferred to syringe 58, without risk of spillage, by inversion of the entire assembly shown in FIG. 4, followed by withdrawal of syringe plunger 60, which action draws the contents of the bottle 10 into the syringe. If any fluid leaks out of pierced stopper 12, it is caught in the bottom 64 of sheath 38.

FIGS. 5-8 show the presently preferred embodiment of a protection device 69 for securely attaching a protected cannula 70 (FIG. 5) to the discharge end of a conventional syringe 72 (FIG. 8), which contains the usual slidable plunger (not shown).

The cannula 70 is press-fitted and sealed with adhesive (not shown) in a longitudinal bore 71 through an annular boss 74, which is press-fitted and sealed with an adhesive (not shown) in a recess 76 in an annular insert 78 press-fitted and sealed with an adhesive (not shown) in a longitudinally extending central stepped bore 80 through a cylindrical protective sheath 82, which has diametrically opposed cutouts 84 at the end of the sheath surrounding the scarf end 86 of the cannula. The slots 84 are sufficiently narrow that it is unlikely a nurse, doctor, or technician could accidentally touch the cannula scarf, and yet each slot 84 is sufficiently wide and deep to accommodate and receive a laterally extending tubing of a conventional Y-site connection, as shown in FIG. 1 of my U.S. Patent 4,834,716.

The end 88 of the cannula opposite from the scarf is squared off and bears against an inwardly extending annular shoulder 89 of the insert 78, which has a coaxial bore 90

which connects the bore (not shown) through the cannula with an enlarged and longitudinally extending socket, or recess, 92 in the end of the insert remote from the scarf. Recess 92 is of conical shape and tapers outwardly away from the cannula at an angle to match that of a conventional tapered discharge nozzle 93 on syringe 72 (FIG. 8). The seating of the squared-off end of the cannula against the shoulder 89 accurately locates the cannula relative to the insert, and facilitates precision assembly of the protection device.

The exterior of insert 78 has an annular shoulder 94 which bears against a matching annular shoulder 95 in the bore 80 extending through the sheath. Thus, when the insert shoulder 94 seats on shoulder 95 of the sheath, the insert is properly positioned within the sheath to locate the scarf of the cannula and the ears of the insert in their required respective positions shown in FIG. 5 to provide precise alignment of the components which make up the device.

The end of insert 78 remote from the scarf of the cannula carries a pair of diametrically opposed and laterally extending ears 96. Each ear 96 is shaped as shown in FIG. 7 to form part of an interrupted male thread 98, which engages internal female threads 100 formed on the inside surface of an annular skirt 102 formed around, and spaced from, the discharge nozzle 93, which has a coaxial stepped bore 104 to permit the discharge of liquid from the syringe by operation of the plunger (not shown) in a conventional fashion. The discharge nozzle 93 projects outwardly beyond the annular skirt 102 to facilitate inserting the nozzle into the tapered recess (socket) 92 of the insert 78 (FIG. 5). A plurality of longitudinally extending grooves 106 (FIG. 9) are formed on the outer surface of the skirt 102 to provide longitudinally extending ridges 108 spaced at intervals of about 6° around the circumference of the skirt.

When the syringe nozzle 93 is inserted into the tapered recess 92 of insert 78, the interrupted male threads 98 on ears 96 engage the internal female threads 100 of the skirt 102, as in a conventional Luer lock of the type shown in U.S. Patent No. 4,737,144 to Choksi. Rotation of the sheath and syringe relative to each other about a longitudinal axis causes the ears to follow the threads inwardly and draw the tapered nozzle 93 into a snug and sealed fit in the tapered recess 92. At the same time, the exterior surface of the skirt 102 makes a sliding friction fit against the inside surface 110 of an annular ring 112 (FIG. 5) formed integrally on the end of the sheath remote from the scarf end of the cannula and terminating flush with the outer end of insert 78. The annular ring 112 is spaced from the exterior of the insert around socket 92 to provide an annular space 113, which receives the Luer lock skirt as the syringe is coupled to the protective device 69. The annular ring 112 also provides backup for the annular skirt 102 and ensures snug, locking engagement of the ears 96 and the internal threads 100. In addition, the longitudinally extending ridges 108 on the exterior surface of the skirt 102 helps prevent inadvertent backing out or disengagement of the ears 96 from the internal threads. Thus, the protected cannula is easily and firmly secured to the discharge end of the syringe, which can now be safely loaded with medication, as described above with respect to FIGS. 1-4.

The present invention affords several significant safeguards. First, the insertion of the upper portion 22 of the stopper 12 (FIG. 2) within the sheath provides alignment and precise needle puncture so that leakage of toxic material is avoided. Without such alignment, the repeated punctures necessary for typical multiple-dose vials results in not one, but several holes in the diaphragm, causing leakages and spills. This cannot

happen where the scarf of the cannula is aligned by the sheath with the stopper before the scarf contacts the diaphragm, and therefore, the same hole in the diaphragm is repeatedly and consistently struck.

Second, in filling the syringe, the container 10 is always inverted and above the syringe, which has the cannula pointed up. Even if a small leakage occurred around the cannula via the hole created by the cannula piercing the diaphragm, these drops would be caught inside the sheath 38 and could not spill on the hands and fingers.

Third, the diametrically opposed cutouts on the sheath permit safe injection of the toxic contents of the syringe at the "Y" site of an I.V. set, as is explained in my above-mentioned U.S. Patent No. 4,834,716.

The protective device shown in FIGS. 5-8 also makes it possible to connect the end of the cannula remote from the scarf to any conventional syringe, whether it has a Luer lock connection or not. For example, the syringe could be of the type which has only a tapered nozzle of the type shown in FIG. 8 and which is not surrounded by a skirt 102 with internal threads 100. Thus, a syringe of that more simple type is quickly connected to the protected cannula of this invention by making a tight friction fit of the syringe nozzle into the tapered recess or socket 92 of the protective device. However, the preferred arrangement is to use a syringe with the skirt and internal threads so that the protective device for the oannula can be firmly engaged with and locked to the syringe.

In addition, hospitals now generally instruct nurses and others not to recap cannulas, but rather to discard them into special containers. Most accidental punctures come from used cannulas when personnel are trying to recap them. The present invention, because the cannula scarf is recessed within the sheath, eliminates need to try to recap an exposed scarf. Moreover, even after the protected

cannula of this invention is discarded in an uncapped state, it poses no threat because the scarf is enclosed within the sheath.

CLAIMS

1. A protective device for enclosing the scarf of a cannula, the device comprising:

an elongated sheath having a bore extending through it;

an elongated cannula having a scarf end;

means mounting and sealing the cannula in the bore of the sheath and with the scarf end of the cannula located within and adjacent one end of the sheath, the end of the sheath adjacent the scarf end of the cannula having at least one cutout portion which can receive the edge of a flexible bag or a flexible tubing connected to a Y-site for intravenous injection; and

a socket carried by the sheath at the end of the cannula remote from the scarf, the socket having an opening through it and connected to an opening through the cannula, the socket opening tapering outwardly away from the cannula for receiving a tapered nozzle on a syringe.

2. A protective device according to claim 1 which includes two cutouts in the end of the sheath adjacent the scarf end of the cannula.

3. A protective device according to claim 2 in which the two cutouts are diametrically opposed.

4. A protective device according to claim 1, 2, or 3 which includes longitudinal grooves on the outside of the sheath.

5. A protective device according to claim 1, 2, or 3 which includes outwardly extending ears on the socket for engaging internal threads on a skirt at the discharge

end of a syringe and surrounding a nozzle connected to the syringe.

6. A protective device according to claim 5 in which the sheath is disposed around and spaced from the socket and ears to form an annular space for receiving an annular skirt on a syringe and around a nozzle on the syringe.

7. A protective device according to claim 6 which includes a syringe with a nozzle, and a skirt on the syringe around the nozzle and constructed and arranged for making a slip-fit against the inside surface of the sheath around the socket.

8. A protective device according to claim 7 which includes an irregular surface on the outer portion of the syringe skirt.

9. A protective device according to claim 7 which includes longitudinally extending grooves on the outer surface of the syringe skirt.

10. A protective device substantially as herein before described with reference to any one of the accompanying drawings.

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